UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,709	09/27/2002	Sheena M. Loosmore	1038-1138 MIS:jb	5961

24223 7590 06/15/2006

SIM & MCBURNEY
330 UNIVERSITY AVENUE
6TH FLOOR
TORONTO, ON M5G 1R7
CANADA

EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No.	Applicant(s)	
	09/806,709	LOOSMORE ET AL.	
	Examin r	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communicati n appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,9-11 and 13-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,9-11 and 13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/31/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group K in the reply filed on April 3, 2006 is acknowledged.

Amendment Entry

2. The amendment filed April 3, 2006 has been entered. Claims 1 and 15 have been amended. Claims 3-8, 12 and 16-36 have been cancelled. Claims 1-2, 9-11, 13-15 are under consideration in this office action.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because the post office address of Michael Klein has non-initialed and/or non-dated alterations which have been made to the oath or declaration. See 37 CFR 1.52(c).

Specification

4. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a deposit rejection.

The specification lacks complete deposit information for the deposit of vector wherein the plasmid is referred to as DS-1046-1-1. Because it is not clear that cell lines possessing the properties of the plasmid are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the claims require the use of the plasmid, a suitable deposit for patent purposes is required. Without a publicly available deposit of the above cell line, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the cell line is an unpredictable event.

If a deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her

signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of deposit and the complete name and full street address of the depository is required.

If the deposit has not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR §1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

(c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the depository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of a biological material not made under the Budapest Treaty must be filed in the application and must contain:

1) The name and address of the depository;
2) The name and address of the depositor;
3) The date of deposit;
4) The identity of the deposit and the accession number given by the depository;
5) The date of the viability test;
6) The procedures used to obtain a sample if the test is not done by the depository; and
7) A statement that the deposit is capable of reproduction.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the plasmid described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundack, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR §1.801-1.809 for further information concerning deposit practice.

6. Claims 10-11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 10 recites the limitation "the *cer* gene" in the claim. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-2, 9-11 and 13-15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 9-11, 13-15 of U.S. Patent No. 6,432,669. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The patented claims are drawn to a nucleic acid molecule comprising a

promoter functional in *E. coli* and operably coupled to a modified operon of a non-typeable strain of *Haemophilus influenzae* comprising a modified gene A, a B gene and a C gene and which encodes a high molecular weight (HMW) protein, wherein the modified A gene of the operon contains only a nucleic acid sequence which codes for a mature HMW protein of non-typeable strain of *Haemophilus* and lacks the segment of the A gene which encodes the leader sequence for the HMW protein. The dependant claims are drawn to the T7 promoter, the inclusion of additional nucleic acid sequences, the *cer* gene, a plasmid vector and the same deposited plasmid vector.

The instant claims are drawn to a nucleic acid molecule comprising a promoter functional in *E. coli* and operably coupled to a modified operon of a non-typeable strain of *Haemophilus influenzae* comprising a modified gene A, a B gene and a C gene and which encodes a high molecular weight (HMW) protein, wherein the modified A gene of the operon contains only a nucleic acid sequence which codes for a mature HMW protein of non-typeable strain of *Haemophilus* and said sequence is SEQ ID NO:68 or the nucleic acid sequence codes for SEQ ID NO:69. The dependant claims are also drawn to the T7 promoter, the inclusion of additional nucleic acid sequences, the *cer* gene, a plasmid vector and the same deposited plasmid vector.

The claims of both are drawn to a nucleic acid molecule comprising a promoter functional in *E. coli* and operably coupled to a modified operon of a non-typeable strain of *Haemophilus influenzae* comprising a modified gene A, a B gene and a C gene and which encodes a high molecular weight (HMW) protein, wherein the modified A gene of the operon contains only a nucleic acid sequence which codes for a mature HMW

protein of non-typeable strain of *Haemophilus*. Furthermore, both claims are also drawn to the same T7 promoter, the inclusion of additional nucleic acid sequences, the *cer* gene, a plasmid vector and deposited plasmid vector. Thus, the nucleic acid molecules are not patentably distinct from either patent, since the claims of the patent encompass the instant claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-2, 9 and 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Barenkamp et al., (1994).

The instant claims are drawn to a nucleic acid molecule comprising a promoter functional in *E. coli* and operably coupled to a modified operon of a non-typeable strain of *Haemophilus influenzae* comprising a modified gene A, a B gene and a C gene and which encodes a high molecular weight (HMW) protein, wherein the modified A gene of the operon contains only a nucleic acid sequence which codes for a mature HMW protein of non-typeable strain of *Haemophilus* and said sequence is SEQ ID NO:68 or the nucleic acid sequence codes for SEQ ID NO:69. The dependant claims are also drawn to the T7 promoter, the inclusion of additional nucleic acid sequences, and a plasmid vector.

Barenkamp et al., teach genes encoding high-molecular weight adhesion proteins of non-typeable *Haemophilus influenzae* are part of gene clusters. For plasmid subcloning studies, representative DNA was subcloned into the T7 expression plasmid (page 3320). This vector contained the T7 RNA polymerase promoter, just as required by the claims (page 3220). The authors analyzed the flanking regions of the *hmw1A* and *hmw2A* structural genes and found that both genes are flanked by two additional downstream open reading frames designated *B* and *C* (abstract). The nucleotide sequences of the *B* and *C* genes was determined (page 3221). The complete nucleotide sequence is shown in Figure 1, while Figures 2 and 3 have the *B* and *C* gene sequences respectively. The sequences disclosed by Barenkamp et al., have sequence identity to SEQ ID NO:68 and 69, just as required by the claims. Figure 4 shows the locations of the *A, B* and *C* genes while plasmid pHMW1-15 contains all three genes. Plasmid pHMW 1-14 contained the full length insert, including the genes designated hmw1 and hmw2, these genes encode high molecular weight proteins from non-typeable *H. influenzae* (see abstract and Figure 1 and 4). Therefore the art teaches a nucleic acid molecule further comprising an additional sequence encoding mature HMW proteins just as required by the claims.

Prior Art

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Barenkamp et al., (1992) teach cloning, expression and DNA sequence analysis of genes encoding nontypeable *Haemophilus influenzae* High-

molecular weight surface-exposed proteins. Loosmore et al., (US Patent 6,849,447) teach protective recombinant *Haemophilus influenzae* high molecular weight proteins.

Conclusion

11. No claims allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ja-Na Hines
June 7, 2006

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600